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UNCLAS SECTION 01 OF 03 WARSAW 000259

SENSITIVE
SIPDIS

STATE PASS TO USTR
USTR FOR DWEINER AND JCHOE GROVES
STATE FOR EUR/CE AND EEB/TPP/IBE TMCGOWAN, JURBAN

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TAGS: ETRD ECON KIPR PL
SUBJECT: SPECIAL 301 REVIEW: SUPPLEMENTAL INFORMATION FOR
POLAND

REF: A. WARSAW 225
¶B. 08 WARSAW 237

¶1. (SBU) Summary: Removing Poland from the Special 301 Watch List now would acknowledge progress on traditional intellectual property rights (IPR) issues, and -- if the USG decides in the future to use the Special 301 process to draw attention to market access issues like those troubling the innovative pharmaceuticals industry -- re-listing Poland in the future would focus attention on those problems in a way that simply keeping Poland on the List will not. Poland was moved from the Priority Watch List to the Watch List in 2004. The sting of being on the Watch List has faded, and announcements that Poland is still on the list pass by with little public notice. However, keeping Poland on the List despite advancements like closing the Warsaw Stadium does contribute to fatigue and cynicism regarding the Special 301 process among Polish officials responsible for IPR. The pharmaceuticals industry has some legitimate market access grievances, but not all complaints are equal. In reviewing the industry's Special 301 submission, the USG's focus ought to be on current problems, with real commercial significance, and which do not simply reflect normal cost containment measures common in European health care systems. End summary.

Poland and the Watch List

¶2. (SBU) Information is not available at post regarding when Poland was first added to the Watch List. It was on the Watch List in 2002, and was moved to the Priority Watch List in 2003. The Special 301 report that year stated, "the main concern substantively with Poland is the lack of political will by the Polish government to shut down the open air market inside the Government-owned Warsaw Stadium, which is awash in pirated optical media products and counterfeit goods." In 2004, after an out-of-cycle review, Poland was moved back to the Watch List, because Poland initiated raids at the Warsaw Stadium, strengthened its copyright law, passed legislation regulating optical disc production and acceded to the WIPO Internet Treaties. Poland has been on the Watch List every year since 2004.

¶3. (SBU) The 2008 report briefly acknowledged closure of the Warsaw Stadium. This milestone has not been otherwise recognized or rewarded in the Special 301 process.

Resetting the Watch List's Effectiveness

¶4. (SBU) The effectiveness of the Watch List as a tool to enhance IPR protection in Poland has waned with time. Last year's announcement that Poland would be maintained on the Watch List received almost no media attention, while Polish officials charged with protecting IPR greeted the announcement with frustration and cynicism, questioning whether there were any circumstances that would lead the USG to take Poland off the list.

¶5. (SBU) We understand Washington officials are considering whether to increase the weight in the Special 301 process placed on market access issues, such as those that confront the innovative pharmaceuticals industry in Poland. Simply maintaining Poland on the Watch List year after year, even if the USG states it is now because of market access issues, will generate little or no public discussion in Poland and be seen by Polish officials handling IPR as the USG moving the goal posts. In contrast, taking Poland off the Watch List now would receive public attention and recognize progress on traditional IPR issues. If market access issues caused Poland to be restored to the Watch List next year, that too would be news that would receive media coverage. Also, it would focus political attention on the problems in the Health Ministry in a way that simply keeping Poland on the Watch List will not.

PhRMA's Special 301 Submission: Some Observations

¶6. (SBU) As part of this year's Special 301 process, PhRMA plans to host a briefing for the interagency on March 11. As

noted in post's Special 301 recommendation, the innovative pharmaceuticals industry in Poland has some legitimate market access grievances (ref A). Many of these are addressed in PhRMA's Special 301 submission. However, not all complaints are equally valid.

¶7. (SBU) Discovery Rights in Patent Enforcement Litigation: PhRMA's submission states, "The Industrial Property Law does not contain discovery rules (provided in Copyright Law for instance), which would facilitate establishment of patent infringement." An official from the Polish Patent Office told EconOff, "that claim is not true." In 2007, an amendment to the Industrial Property Law added discovery provisions to Article 286 bis, in accordance with the requirements of the EU's Enforcement Directive (2004/48/EC of April 29, 2004). Article 286 bis allows a rights holder to request a court order compelling the allegedly infringing party to provide information on the origin and distribution networks of the allegedly infringing goods or services. The court can also order discovery of information in the hands of third parties. An English language translation of the Industrial Property Law, including Article 286 bis, is available on the website of the Polish Patent Office.

¶8. (SBU) Damages for Lost Profits: PhRMA's submission states, "The current damages awarded for intellectual property rights violations are inadequate compensation for infringements, as the right holder is rarely permitted to recover its profits. This clearly fails to comply with TRIPS Article 45." EconOff consulted a Polish attorney with extensive experience representing rights holders in IPR-related litigation. He disagreed with PhRMA's claim, stating Polish laws and regulations are quite good in allowing full recovery of damages. The Copyright Law allows double or treble damages, while the Industrial Property Law allows a party to claim damages equivalent to the profits that would have been received under a licensing agreement for use of the patent. He stated that Polish judges rule in

accordance with the law, provided damages have been proved. Polish criminal law also allows for a judge to require partial or total restitution.

¶9. (SBU) The Ghost List: PhRMA's submission notes that on the eve of EU accession, in 2004, the Polish government granted conditional market approval to the so-called "ghost list" of generic products with incomplete dossiers, and then states, "PhRMA member companies are concerned that MoH may use a similar approach in 2008 (sic) to issue conditional re-registrations for older generics when the transitional period allowed for upgrading of old dossiers comes to an end." Post noted last year that we saw no foundation for this concern. (Ref B) Since then, the transitional period has ended. As PhRMA notes elsewhere, producers of some older generics chose not to bring the dossiers for their products up to the EU standards, leading the Ministry of Health to de-list 79 drugs from the reimbursement list in July 2008. We do not see any basis for claiming that the Ministry acted in this matter in a way harmful to the interests of innovative pharmaceuticals producers. The EU infringement proceeding regarding the original "ghost list," from 2004, is still pending.

¶9. (SBU) The 13 Percent Price Cut: In 2006, the Polish government instituted a 13 percent across-the-board price cut on imported pharmaceutical products. In response to allegations that the price cut violated national treatment obligations, in November 2007 the government reduced the price it pays domestic producers for drugs manufactured using imported inputs. An EU infringement proceeding regarding the price reduction is still pending. However, in commercial terms, industry contacts state this is ancient history. The price cuts have long since been absorbed, associated losses written off, and all of the major U.S. pharmaceuticals companies continue to operate in Poland.

¶10. (SBU) Anti-Corruption Measures: The PhRMA submission states, "Anyone wishing to meet a MoH representative must do so by formal request, with an attached, binding agenda. At the meeting, at least three MoH representatives must be present, and the meeting will be either recorded or documented with minutes." The submission then correctly notes that this policy has made it more difficult to meet with Ministry officials, but fails to mention that these measures are designed to end long-standing allegations of

corruption in the drug approval process. Innovative pharmaceutical companies have long alleged that Polish generics producers had a corrupt grip on Ministry officials. While the new anti-corruption measures -- which apply to both foreign and Polish producers -- have made it more difficult to maintain contact with Ministry officials, there is significantly more transparency regarding those contacts that do occur.

¶11. (SBU) Restrictions on Sales Calls: At the end of 2008, the Health Ministry adopted a regulation prohibiting sales calls on doctors and hospitals during working hours. The regulation was based on a similar measure in effect in Sweden, and post understands that other European countries with government-financed health care systems, such as the United Kingdom, also regulate the frequency of pharmaceuticals sales calls on physicians.

¶12. (SBU) Fixed Prices and Margins: The PhRMA submission states, "An example of a discriminatory government pricing activity which affects U.S. and other foreign pharmaceutical companies is the planned amendment to the Pricing Act of the Pharmaceutical Law, which would formally define selling price and fixed margins." The bill has not yet been introduced into the Polish parliament. More importantly, as one pharmaceuticals company general manager told EconOff, fixed prices and margins are part of the medical system in 20 other EU Member States.

¶13. (SBU) Poland is not unique in presenting market access issues for the pharmaceuticals industry. In the general introduction to its Special 301 submission, PhRMA states, "The government entities responsible for pricing and reimbursement in most countries tend to be highly opaque bureaucracies, and the process of obtaining a government-approved price can be lengthy." The situation in Poland should be assessed in light of the general European background. While Polish spending on health care has been increasing (Poland now spends PLN 11 billion per year (about USD 3 billion) on pharmaceuticals), the cost of pharmaceuticals also continues to increase. The Polish government has to make tough policy choices regarding which drugs to fund, and at what level. While pharmaceuticals companies often assert that they would be happy with a transparent process, even if it led to decisions not to fund their drugs, in practice they seem to resent all government measures aimed at cost containment, as these also inevitably limit drug companies' sales.
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